United States Senate
WASHINGTON, DC 20510

August 18, 2022

The Honorable Lloyd J. Austin III
Secretary of Defense
U.S. Department of Defense

The Honorable Robert M. Califf, MD
Commissioner
Food and Drug Administration

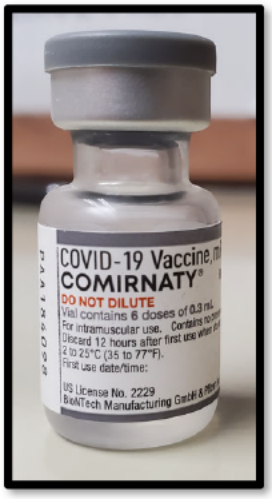
Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention

Dear Secretary Austin, Commissioner Califf, and Director Walensky:

Nine Department of Defense (DoD) whistleblowers recently provided my office with information that raises questions about the manufacturing and labeling of COVID-19 vaccines distributed to service members.[1] These new whistleblower allegations must be fully addressed by DoD, the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC).

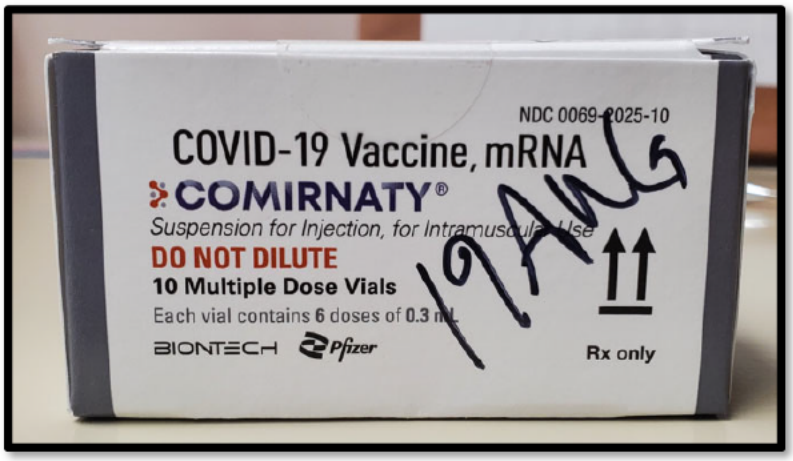
Lt. Chad Coppin, who is a commissioned officer in the U.S. Coast Guard, disclosed that on June 10, 2022, his base located in Juneau, Alaska received "a shipment of 60 Comirnaty vials packaged in six boxes of ten vials."[2] These vials included the vaccine lot number FW1331.[3] Lt. Coppin noted that, "[p]rior to this date, only emergency use authorization shots [had] been available[.]"[4] Lt. Coppin provided my office with pictures of one of the Comirnaty vials and boxes his base received:

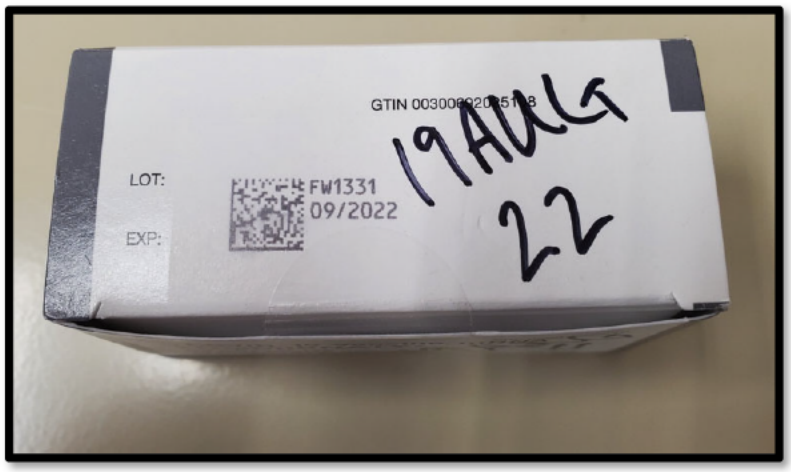
Pictures of Comirnaty Vial (taken on June 10, 2022)



[1] Letter from nine Dep't of Defense whistleblowers, Aug. 15, 2022 (enclosed).
[2] Chad Coppin disclosure to Sen. Ron Johnson (on file).
[3] *Id.*
[4] *Id.*

Pictures of Comirnaty Box (taken on June 10, 2022)





Lt. Coppin reported that he attempted to determine the shipping and manufacturing locations of these specific vaccines.[5] He explained to my office that the medical staff at his base informed him that the vials were shipped from Ft. Detrick in Maryland.[6] Lt. Coppin stated that he contacted Ft. Detrick to ask about the manufacturing location of the vials and was told that these vials came from a "Pfizer plant" located in Kalamazoo, Michigan.[7]

Lt. Coppin then called Pfizer directly to ask about the manufacturing location of the specific vaccine lot number for these vials: FW1331.[8] A Pfizer customer service representative apparently told him that this lot was manufactured in France on January 28, 2022 and expires on December 31, 2022.[9] Lt. Coppin disclosed to my office that, "The significance of the France manufacturing location is that it is not an authorized manufacturing location as per the FDA's Comirnaty [Biologics License Application (BLA)] Supplement Approval letter dated December 16, 2021."[10] That letter approved a "30 microgram dose formulation (Tris/Sucrose) of

[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*

Comirnaty" to be manufactured at the "Pfizer Manufacturing Belgium NV, Purrs, Belgium facility."[11] Any Comirnaty vaccine lots that are manufactured outside of the FDA-approved manufacturing locations and distributed to U.S citizens raises significant legal and health-related concerns.

In addition to the lack of clarity relating to the manufacturing location of vaccine lot FW1331, another DoD whistleblower raised questions about whether this specific vaccine lot is mislabeled as "Comirnaty." 1Lt. Mark Bashaw, who is a commissioned officer in the U.S. Army, found that the lot number contained on these "Comirnaty" vials—FW1331—matched a lot number on a CDC database listing Emergency Use Authorization (EUA) vaccine lots.[12]

According to CDC, this database, which is called the COVID-19 Vaccine Lot Number and Expiration Date Report, "contain[s] all lots for COVID-19 vaccines made available under [EUA] for distribution in the United States."[13] 1Lt. Bashaw disclosed to my office that he downloaded this database and found that it included vaccine lot FW1331.[14] DoD, FDA, and CDC must provide a thorough explanation for why a vaccine lot with the "Comirnaty" label would be listed on a database that is meant to display vaccine lots associated with the EUA.

Lt. Coppin, 1Lt. Bashaw, and the additional seven DoD whistleblowers who brought this information to my attention have exercised their right to talk to Congress. Any retaliatory actions taken against these individuals will not be tolerated and will be investigated immediately. DoD, FDA, and CDC owe our service members complete transparency regarding the COVID-19 vaccines that the Biden administration has forced upon them. With this in mind, I request that you provide the following information:

1. Was vaccine lot FW1331 manufactured at the Pfizer facility located in Belgium? If not, why not?

2. Why is vaccine lot FW1331, which is labeled "Comirnaty," listed on a CDC database ("COVID-19 Vaccine Lot Number and Expiration Date Report") for EUA vaccine lots?

3. Was vaccine lot FW1331 created under the EUA? If so, why is it labeled "Comirnaty"?

4. Please identify the vaccine lot numbers, in addition to FW1331, that are labeled "Comirnaty" and have been distributed to U.S. military bases *and* are also listed on CDC's "COVID-19 Vaccine Lot Number and Expiration Date Report."

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[11] Letter from Jerry Weir, Food and Drug Administration, to Amit Patel, Pfizer Inc , Dec. 16, 2021, https://www.fda.gov/media/154939/download.
[12] Mark Bashaw disclosure (on file).
[13] COVID-19 Vaccine Lot Number and Expiration Date Report, Centers for Disease Control and Prevention, https://vaccinecodeset.cdc.gov/LotNumber.
[14] Mark Bashaw disclosure (on file).

Please provide this information as soon as possible but no later than September 1, 2022. Thank you for your attention to this matter.

Sincerely,

Ron Johnson
United States Senator

cc: The Honorable Sean O'Donnell
Acting Inspector General
Department of Defense

The Honorable Christi Grimm
Inspector General
Department of Health and Human Services

Enclosure

Enclosure

15 August 2022

Memorandum for all Members of Congress from Concerned Service Members

Subject: Whistleblower Report of Illegal Department of Defense Activity

Encl: (1) Pfizer Announcement that Comirnaty will not be produced, NIH Website, 13 Sep 2021
(2) Defense Health Agency Freedom of Information Act Response 21-00359, 20 Apr 2022
(3) Assistant Secretary of Defense Health Affairs, Mandatory Vaccination of Service Members using Pfizer-BioNTech and Comirnaty COVID-19 Vaccines, 14 Sep 2021
(4) Unsigned Proposed Mandatory Vaccination of Service Members Replacement Memo submitted to Dr. Terry Adirim on 20 Oct, 2021
(5) Component Comment Review Matrix for Proposed Military Vaccination of Service Members Memorandum, Submitted 29 Oct 2021
(6) Coker v. Austin, USDC Northern District of Florida, Document 88-1, 20 May 2022
(7) Military Whistleblower Photographs of "Comirnaty-Labeled" vaccine product taken at USCG Sector Juneau, AK, 10 Jun 2022
(8) CDC COVID-19 Vaccine Lot Number and Expiration Date Database
(9) Declaration of 1LT Mark C. Bashaw, US Army, 4 Aug 2022
(10) FDA Comirnaty Supplement Approval, 16 Dec 2021
(11) Declaration of LT Chad R. Coppin, USCG, 30 Jul 2022

1. The undersigned hereby submit this report under the Military Whistleblower Protection Act (10 USC § 1034) as duty requires us to advocate for the rights of all American citizens and for the rights of service members across all branches of the Armed Forces. Pursuant to 28 USC § 1746, the undersigned declare under penalty of perjury as follows:

2. Since 24 August 2021, the Department of Defense (DoD) has unlawfully administered Emergency Use Authorized (EUA) products (i.e., products authorized but not approved by the Food and Drug Administration (FDA)) *as if* they were fully licensed FDA approved products. Military members have not been allowed to exercise their legal right to refuse EUA products, despite the Department of Justice's (DOJ) assertion that "Comirnaty-labeled" vaccines only became available for the DoD to order on 20 May 2022. Evidence also exists that the new "Comirnaty-labeled" products are not FDA approved in accordance with applicable laws.

3. Americans never lose the right to legally refuse an EUA product. EUA law 21 USC § 360bbb imposes significant responsibilities upon the government to inform Americans of their rights. The only exception to the government's duty to inform citizens of their rights is in a narrowly defined presidential waiver process for the military per 10 USC §1107a. This exception only waives the required condition that service members be informed of their right to refuse an EUA product. The 105th Congress passed 10 USC § 1107 into law as part of the Fiscal Year 1998 National Defense Authorization Act as a result of the injuries sustained by Gulf War veterans due to forced administration of investigational new drugs. This was quickly followed by the passage of 10 USC § 1107a, which specifically addressed use of EUA products. Similar to the Constitutional violation of failing to provide a suspect their Miranda Rights, not informing a potential recipient of their right to accept or decline an EUA product, either by presidential waiver or by omission, does not remove the underlying rights protected by statute and the Constitution.

4. Prior to the administration of an EUA product, the recipient is required to be informed inter alia of the option to accept or refuse administration of the EUA product, as codified in 21 USC § 360bbb-3(e)(1)(A)(II)(iii). This right is a required condition that the Secretary of Health and Human Services (HHS) shall include for the authorization of any unapproved product covered by an emergency declaration. This means that by law, no one can mandate EUA products and the Government must inform recipients of their right to refuse. Service members are not being informed of the option to refuse administration of EUA products, nor are they provided with any other required information such as the risks associated with the product. Instead, military leadership is coercing service members into accepting administration of EUA products through unlawful threats against their careers and livelihoods. The failure of numerous appeals to leadership, Equal Opportunity complaints, Article 138 requests for redress, Inspector General complaints, and Congressional inquiries filed by the undersigned and those similarly situated, indicate that the military has no intention of following the law or their own regulations. Accordingly, Congress must act swiftly to end this unlawfulness and preserve the rights, readiness, and character of the military.

5. The law justly enshrines the principle that where there is risk, there must be legally effective informed consent. There must be full disclosure of relevant information and it must be absent coercion and undue influence. For risky medical products, like EUA pandemic products, Congress provides complete liability protection against any claim of loss for all persons and entities who are involved in the manufacture, distribution, planning, or administration of those products. 42 USC § 247d-6d(a)2(A) defines loss very broadly, listing everything from death to fear of emotional injury to property loss from business interruptions. For clarity, persons and entities covered by liability protections include product developers, manufacturers, and administrators (health care personnel), as well as all related governmental personnel at the local, state, and federal levels, including members of Congress and the DoD. Accepting administration of an emergency use product means the individual accepts all the health, legal, financial, and medical risks arising from that product.

6. Injured recipients (or their families, in the event of death) who voluntarily received an EUA product only have one legal method to recoup losses: by filing a compensation claim through the Countermeasure Injury Compensation Program (CICP) as per 42 USC § 247d-6e. To date, there are 8,808 total COVID-19 related claims in the CICP. Claims of loss typically have a benefit cap of $379,000, however HHS has not granted a single dollar to those 8,808 claimants.[1] Due to complete liability protections during declared emergencies, neither the Executive Branch of government nor any manufacturer, developer, producer, or administrator of covered products have any incentive to ensure the safety or efficacy of the products they are providing. The pandemic demonstrated that without congressional action the executive branch and administrative state will continue to baselessly declare and extend emergencies, exercising powers that exceed federal authority.

7. In a memorandum issued on 9 August 2021, Secretary of Defense (SECDEF) Lloyd Austin indicated his comprehension of EUA law, stating, "I will seek the President's approval to make the vaccines mandatory no later than mid-September, or immediately upon the U.S. Food and Drug Administration (FDA) licensure, whichever comes first."[2] On 23 August 2021, the FDA approved

[1] https://www hrsa.gov/cicp/cicp-data#table-1, accessed 10 Aug 2022
[2] https://media.defense.gov/2021/Aug/09/2002826254/-1/-1/0/MESSAGE-TO-THE-FORCE-MEMO-VACCINE.PDF, accessed 10 Aug 2022

(fully licensed) the first COVID-19 vaccine under the trade name Comirnaty®. Of interest, the FDA ended its legal marketing status that same day.[3] The next day, SECDEF issued a memorandum that stated "[m]andatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance."[4] Shortly thereafter, in a posting on the National Institute of Health website, enclosure (1), Pfizer announced they would not produce any of the licensed product "over the next few months while EUA authorized product is still available and being made available for U.S. distribution." For nine months afterwards, this lack of fully licensed product has been confirmed by hundreds of service members, who have provided military leadership hundreds of complaints, many with photo evidence, indicating all vials found in Military Treatment Facilities were EUA products. A Freedom of Information Act (FOIA) response from the Defense Health Agency (DHA) in April 2022, enclosure (2), confirmed DHA had no record of "Comirnaty" COVID-19 vaccines being ordered, received, in stock, available, or administered to any service member by any service branch (Army, Navy, Marine Corps, Air Force, or Coast Guard).

8. Subordinate commanders failed to adhere to both the law and to SECDEF guidance regarding licensure of products. Military commanders ordered service members to become vaccinated against COVID-19 without consideration for the EUA status of available vaccines. The mandate also set an unrealistic policy of 100% vaccination. DoD instructions clearly provide for religious accommodation and medical exceptions to vaccines, nearly 100% of which are being systematically disapproved. Federal courts have acknowledged that the military's implementation of these instructions have been so egregious that numerous injunctions have been levied against the DOD for violating the Constitution, Religious Freedom Restoration Act, and DoD policy.

9. The DoD induced confusion by publishing memoranda asserting that the FDA-approved Comirnaty® could be used interchangeably with EUA products. Assistant Secretary of Defense for Health Affairs (ASD HA), Dr. Terry Adirim, wrote a 14 September 2021 memorandum, enclosure (3), stating "these two vaccines are interchangeable and DoD health care providers should use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine." In her memorandum, she cited the FDA's Q&A website to justify use of EUA Pfizer-BioNTech vaccines in lieu of Comirnaty®. The website provided medical advice regarding the use of the EUA product to complete a "vaccination series," stating medical providers could use the two products "interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns."[5] The FDA website did not address the legal difference between the products, nor was it a determination of biosimilarity or interchangeability, which has specific requirements per 42 USC § 262(k) - Licensure of Biological Products as Biosimilar or Interchangeable. The law cites critical requirements for interchangeable products, including that: 1) a sponsor must submit an application for licensure of the biosimilar product, 2) both products become fully licensed before being declared interchangeable, and 3) per 42 USC § 262(k)7(A), "[a]pproval of an application under this subsection [Licensure of Biological Products as Biosimilar or Interchangeable] may not be made effective by the Secretary until the date that is 12 years after

[3] The approval of Comirnaty® listed the marketing beginning and end date as 23 Aug 2021.
[4] https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF, accessed 10 Aug 2022
[5] https://www fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna, accessed 10 Aug 2022

the date on which the reference product was first licensed under subsection (a)." By law, no product may be legally declared interchangeable with Comirnaty® until at least 24 August **2033**. As further evidence, the FDA's authoritative source for approved biologics, the "Purple Book," lists "no interchangeable data at that time" for Comirnaty®.[6] Dr. Adirim, and every military commander who cited her memo as justification for their unlawful orders, ignored the legal distinction between the two products, most notably that one was a licensed product and the other an EUA product, which comes with an inherent right to refuse. This legal distinction was clearly cited by the FDA in every Pfizer BioNTech and Moderna EUA re-issuance letter since full licensure.[7]

10. The DoD cannot claim ignorance with regard to the legal differences between an EUA product and a licensed product that purports to be medically interchangeable but has not become statutorily interchangeable per 42 USC § 262(k). SECDEF statements reflected comprehension of legal requirements associated with EUA products. Additionally, an unsigned memo that was developed by the DoD to replace Dr. Adirim's 14 September 2021 memo, enclosure (4), provided specific guidance that if a service member rejected the EUA product, Health Care Providers should secure and offer the fully licensed product "prior to any punitive action being taken against the Service Member." An official internal review, enclosure (5), provided by reviewers of this memo, demonstrates the subsequent attempt to cover up the DoD's grievous mistake. One comment even acknowledges that this correction "subverts" the current vaccination policy and may open up the service to "increased litigation from individuals who have been mandated since 24 August to be vaccinated." The correction memo was ultimately rejected, demonstrating DoD's awareness and support of illegal prosecution of military members, and a lack of integrity to resolve the situation.[8]

11. When the DOD's unlawful misrepresentation of interchangeability began to fail in federal court, the DoD and DOJ began to allege that the Pfizer EUA vaccine products were compliant with Biologics License Application (BLA) requirements. They coined the term "BLA-Compliant" in an effort to argue that mandating an EUA product was lawful. BLA requirements, however, include an obligation to properly label biologic products. EUA products are not compliant with BLA requirements because the EUA label does not match the BLA approved product label (i.e. Comirnaty®). Senior DoD officials, supported by the DOJ, misrepresented, circumvented, obfuscated, and ultimately violated U.S. law to achieve the unreasonable and detrimental goal of 100% vaccination of the military. Military leadership's disregard for U.S. law has not been limited to vaccines. COVID-19 test kits[9] and masks[10], all of which are EUA products, have been mandated as well.

12. Until May 2022, EUA products were the only COVID-19 vaccines available to the U.S. military. FDA approved vaccines were not available. In spite of this, military leaders coerced and

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[6] https://purplebooksearch fda.gov/results?query=COVID-19%20Vaccine,%20mRNA&title=Comirnaty, 10 Aug 22
[7] See page 16 of the most recent EUA reissuance letter for an example: https://www.fda.gov/media/150386/download, accessed 10 Aug 2022.
[8] In this same memo, the author admits they are "operating under the belief that the lot issue is a distinction without a difference from a… legal perspective." They also admit that to reverse course and admit "that the distinction does matter would probably require significant remedial actions." See page 5 of enclosure (5) to read these comments.
[9] https://www fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2, accessed 14 Aug 22
[10] https://www fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas, accessed 14 Aug 22

attempted to force administration of EUA products on unwilling service members, pursuing punitive action against many who did not comply. On 20 May 2022, the DOJ filed a memorandum on behalf of the defendants (Austin, et al), enclosure (6), in the Coker v. Austin case in Federal District Court for the Northern District of Florida in which they attempted to undermine the plaintiff's legal standing to challenge in court by asserting that "[w]hile they [the plaintiffs] may believe that FDA-approved vaccines are "not available," the Comirnaty-labeled vaccine is in fact available for DoD to order as of today's date [20 May 2022]." Shortly thereafter, "Comirnaty-labeled" products began appearing in very limited quantities on military installations, including the "Comirnaty-labeled" product seen in enclosure (7). The sudden appearance of "Comirnaty-labeled" vials indicate that the DoD was mandating the use of EUA vaccines for nine months prior to May 2022.

13. In accordance with 21 USC § 360bbb-3(c), the Secretary of HHS may only authorize a product for emergency use if there is no fully licensed product available. The HHS Secretary is further obligated by 21 USC § 360bbb-3(g) to review the progress made by fully licensed products and potentially revoke a product's emergency authorization if a fully licensed product becomes available. If the "Comirnaty-labeled" products identified in enclosure (7) are licensed products, the HHS Secretary should have revoked the various authorizations enabling unapproved EUA biological products to remain on the market. These revocations have not occurred.

14. The status of the new "Comirnaty-labeled" product is also in question. The CDC maintains a database, enclosure (8), of "all lots for COVID-19 vaccines made available under Emergency Use Authorization (EUA) for distribution in the United States."[11] The vial depicted in enclosure (7), which is "Comirnaty-labeled," has the lot number FW1331. This lot number appears in the CDC EUA database as testified by military whistleblower, 1LT Mark Bashaw, per enclosure (9). Misrepresenting an EUA manufactured lot of vaccine product as a fully licensed product is a violation of labeling requirements per 42 USC § 262.

15. Further evidence of potential fraud related to the "Comirnaty-labeled" product pictured in enclosure (7) is Pfizer's admission that the vaccine product with lot number FW1331 was not produced in a BLA approved manufacturing facility. The 16 December 2021 FDA approval letter licensing Comirnaty®, enclosure (10), specifies that the licensed product be manufactured at the Pfizer Manufacturing facility in Puurs, Belgium. Per the testimony provided by LT Coppin in enclosure (11), Pfizer admits that Lot Number FW1331 was actually manufactured in France, not in the approved facility in Belgium. Fully licensed products are required to follow all Biologic License Application requirements. Affixing a "Comirnaty-label" on a product that has not followed all BLA requirements constitutes fraudulent labeling – a federal crime.

16. With regard to fraudulent labeling, 42 USC § 262(b) clearly states that "[n]o person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark." The penalties for such violations are stated in 42 USC § 262(f): "Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment." It is also important to note that fraud voids liability protections and consent agreements. The DoD and its distributed commands (and commanders) may be exposing

[11] Enclosure (8) is the database intro page: https://vaccinecodeset.cdc.gov/LotNumber, accessed 5 Aug 2022

themselves to significant liability by willfully misrepresenting these biologics. Furthermore, as there is no long-term safety data for these products, a link between COVID-19 vaccination and long-term health problems could have a crippling impact on the future readiness of our military. Fraudulent activity and health impacts could result in extraordinary cost to the taxpayer. These challenges add to the DoD's current recruiting and retention crisis brought on by the systemic violation of rights and the destruction of sacred trust with service members.

17. The military is hemorrhaging outstanding military men and women of conscience, who are attempting to defend the rule of law at great personal cost. The DoD has unlawfully discharged thousands of service members for exercising their legal right to decline emergency use products. Ensuring timely DoD adherence to U.S. law requires Congressional action. As the oversight authority, you have the ability to investigate the HHS Secretary's recurring declarations of emergency, as well as potential crimes associated with unlawful administration of EUA products and biologic product labeling fraud. Failure to take swift action will cause continued, irreversible harm to the basic human rights of American citizens while further damaging our national security.

18. Like you, we swore an oath to support and defend the Constitution against all enemies, foreign and domestic. Despite spending our careers focused on foreign enemies, it appears the greatest current threat to our Constitution, to the rule of law, and to U.S. military readiness comes from within. On behalf of service members who share our concerns, as well as the citizens we stand in harm's way to protect, we request that you promptly investigate these matters and hold accountable those found to have acted unlawfully. Please end illegal EUA mandates and all related fraudulent activity to ensure that our military can once again be counted on to uphold the rule of law in support of our Constitution.

Executed on 15 August, 2022.

John S. McAfee
Colonel, USAF

Jon C. Cheek
Lt. Colonel, US Army

Olivia K. Degenkolb
Commander, USN

Robert A. Green Jr.
Commander, USN

David I. Beckerman
Major, USAF

Patrick M. Weir
LCDR, USN

Joshua P. Hoppe
Capt, USMC

Chad R. Coppin
LT, USCG

Mark C. Bashaw
1LT, US Army